

January 2016

Volume 16, Issue 1

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About the MedSun Program:

The MedSun Program, which was launched in 2002 by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), involves the reporting of problems with medical products from a network of approximately 250 hospitals, nursing homes and home health facilities around the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products. MedSun utilizes a secure, on-line system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

Those who are interested in having their healthcare facilities join MedSun may contact medsun@fda.hhs.gov or 800-859-9821 for additional information.

Newly Approved Devices

Recently Approved Devices (searchable listing):

http://www.accessdata.fda.gov/script s/cdrh/cfdocs/cftopic/mda/mdalist.cfm?list=1

Premarket Approval Final Decisions: http://www.fda.gov/MedicalDevices/PmachapproductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm475607.htm

510(k)s Final Decisions:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm475766.htm

In Brief

As of December 16, 2015

For the FDA Enforcement Report containing the most recent Class I, II and III recalls, go to

http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Product-Tabs.cfm?action=Expand+Index&w=12162015&lang=eng

If you see any problems of the type described in these announcements or other device safety issues, please report them through the MedSun reporting system at https://medsun.fda.gov as soon as possible. If you need password information or want to report by phone, please call us at 1-800-859-9821 or e-mail at medsun@fda.hhs.gov.

Recalls and Safety Alerts

Chariot Guiding Sheath by Boston Scientific: Recall

(December 11, 2015)

The recall affects all UPNs of the Chariot Guiding Sheaths. The recall was initiated on November 19, 2015 due to the risk of shaft separation. To date, Boston Scientific has received fourteen complaints for shaft separation, four of which involved separation of the distal shaft. These events occurred during device preparation or use. The most severe outcome of this failure is embolism of device fragments, which could lead to obstruction of blood flow or additional intervention to remove a device fragment.

<u>Inspiration LS, 5i and 7i Ventilator Systems by eVent Medical:</u> Class I Recall

(December 7, 2015)

eVent Medical is recalling the LS, 5i, or 7i Inspiration ventilators because a faulty switch on the ventilators' power board may fail, causing the ventilator to shut down without sounding an alarm. This recall includes all models of eVent Medical LS, 5i and 7i Inspiration ventilators manufactured prior to January 21, 2015. To mitigate the risk of ventilator failure, the firm attached the instructions for removing the potentially faulty component from the power board.

OmniPod Insulin Management System by Insulet: Field Safety Notification

(December 2, 2015)

This Notification is due to a slight increase in the reported cases in which the Pod's needle mechanism failed to deploy or there was a delay in the deployment of the needle mechanism. In the event a needle mechanism fails to deploy, the needle will not be inserted and insulin delivery will not begin. The interruption of insulin delivery may cause elevated blood glucose (hyperglycemia), which, if left untreated, can result in diabetic ketoacidosis (DK

<u>Digital Temple Thermometer (DTT) by K-Jump Health Co., Ltd.:</u> <u>Recall</u>

(December 1, 2015)

Some devices contain a manufacturing problem causing the affected thermometers to display temperatures that are inaccurate and lower than actual body temperatures, which potentially may cause the user or caregiver of the user to delay or forego seeking appropriate care (generally an over-the-counter fever reduction medication) or receive more care than appropriate, when relying solely on the temperature display on the thermometer.

MedSun Small Sample Survey Topic: Breast Tissue Expander (BTE) and Implantable CardioverterDefibrillator (ICD) Interference Final Report

Introduction

A common breast reconstruction technique is tissue expansion, which involves expansion of the breast skin and muscle using a temporary breast tissue expander (BTE). A breast tissue expander is an inflatable breast implant designed to stretch the skin and muscle to make room for a future, more permanent implant. Recently, two articles were published describing cases where implanted BTEs with magnetic port locators came in close proximity to the patient's implantable cardioverter-defibrillator (ICD), which may have caused a suspension of tachycardia therapies. These articles suggest there may be an interaction between the BTE's magnetic injection port and the ICD.

The FDA conducted a small sample survey with cardiac electrophysiologists, breast reconstruction surgeons, medical directors, and risk managers to learn about their experiences with BTEs and ICD interference. The survey questions focused specifically on whether the hospital has experienced interactions between BTE magnetic injection ports and ICDs in patients who have both implants, and whether this issue is considered common knowledge in the hospital community. The survey was intended to help determine if healthcare professionals in the U.S. are aware of or have experienced these issues in their patients.

<u>Methodology</u>

A sample of health care providers from hospitals that participate in FDA's Medical Product Safety Network (MedSun) were queried to obtain detailed perspectives about possible interference between BTEs and ICDs. Respondents from fourteen different hospitals located in all regions of the U.S. participated in the voluntary survey. Ten hospitals involved in the survey have between 100-399 beds and four hospitals have between 400-900 beds. All respondents have experience with BTEs or ICDs.

Overview of Responses

BTE and ICD Interference

Of fourteen respondents, none have experienced an interaction between the BTE magnetic injection ports and ICDs in patients who have both implants. All respondents also say this issue is not considered common knowledge in their professional community. One respondent said even though they haven't had direct issues with BTEs they are aware of the potential interaction because it's noted in their hospital's cardiac and vascular department policy. This policy says

BTEs are not recommended for patients with pacemakers or ICDs due to the possibility that the magnet may suspend ICD therapy or change pacemaker function.

One respondent says that even though the article case studies seem like random occurrences, anything is possible when you place a magnet or metal near an ICD. If a patient is pacemaker dependent, the metal or magnet in the BTE could theoretically shut off the pacemaker causing the patient to faint or die. Another hospital echoes the previous respondent by saying even though this interaction is not well known, there should be awareness amongst cardiologists and electrophysiologists that anything that creates an electromagnetic field in the immediate vicinity of an ICD could cause temporary interference.

Summary

Overall, fourteen hospitals responded to the survey and none have experienced possible interference between BTEs and ICDs. All respondents also say this is not a widely known issue in their professional communities. One respondent is aware of the possible interaction because their hospital policy says BTEs are not recommended for patients with pacemakers or ICDs.

Even though respondents say this specific interaction is uncommon, there should be general awareness amongst cardiologists and electrophysiologists that any object capable of creating an electromagnetic field while near an ICD could cause temporary interference. One hospital also notes that several medical device companies are either working on or already have ICDs or pacemakers that are MRI compatible.

Survey Limitations

Although the findings add to FDA's knowledge of clinical experiences, and provide perspectives about possible interference between BTEs and ICDs, the small sample size of the survey limits the findings. In view of this limitation, the respondents' perspectives may not represent the perspectives of all cardiac electrophysiologists, breast reconstruction surgeons, medical directors, and risk managers. Therefore, these findings represent only one piece of information. No conclusions can be made about possible interference between BTEs and ICDs based on this report alone. Instead, the report should be considered along with other information that may include adverse event reports, scientific publications, enforcement/compliance information, and other data sources that are part of FDA's monitoring of device performance.

Surveying device users is one of many tools the FDA uses to evaluate the public health impact of potential problems associated with the use of medical devices. Typically, small sample surveys are used to collect qualitative information on post-market experiences of clinicians or facilities with medical device performance or use. The FDA selects survey respondents based on their

experience with the topic or device, their availability, and their willingness to participate.

The FDA makes our scientific, medical, nursing, and engineering staff aware of the survey results as needed. If the FDA believes there is a significant risk of adverse events as noted from the survey, we will combine those results with data gained from other sources. The FDA will work with the manufacturers and health care provider organizations to make important information known to the clinical community. Additionally, the FDA continues to work with manufacturers to ensure the development, testing, and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, the FDA may convene a group of clinical, scientific, and regulatory experts to discuss any necessary action.

HIGHLIGHTED REPORTS

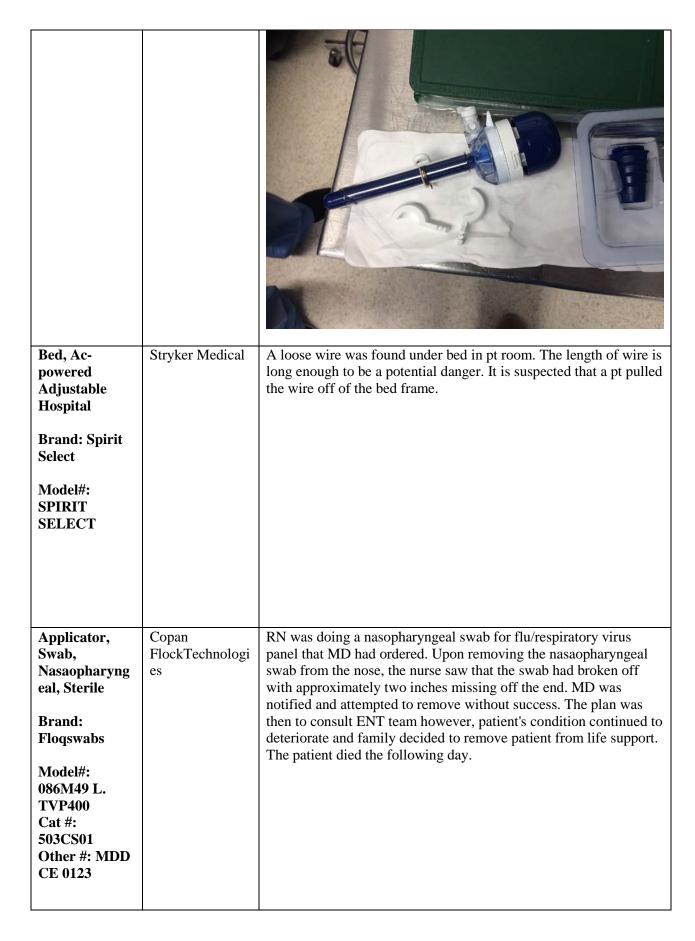
The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during December 2015. The reports are displayed within clinical specialty areas based on analysis of the information submitted. The reports are presented as submitted by MedSun Representatives and in some instances have been summarized and/or edited for clarity.

A database of all MedSun reports can be found at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm



The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as less than 21 years of age

Device	Manufacturer	Problem
Laparoscope,	Covidien	The pediatric surgeon is using a Bluntport for Hasson approach on
General		the belly; while the trocar is being used at the beginning of the
&Plastic		case, the part that is designed to hold the suture broke off. A new
Surgery		trocar was opened to replace the broken one. Nothing of the broken
		pieces went inside the abdomen.
Brand:		
Versaone		Manufacturer response for Covidien Bluntport Hasson 12mm
		trocars, (brand not provided) (per site reporter)
Lot #:		=======================================
J5g0926x		
Cat #:		Covidien Hasson trocar broke; the vendor was notified today.
BPT12STS		
		Please see picture below:
%		



System, X-ray, Tomography, Computed

Brand: Lightspeed

Xtra

GE Healthcare

The GE doctor's monitor that is used during the performance of Interventional Radiology (IR) guided biopsies has a defect on the screen that could potentially result in an error of wrong site procedure.

The GE monitor contains fonts that are sans serif (without feet)-this causes the monitoring screen letters and numbers to be confused. The example that almost created an error a couple of weeks ago, was that the letter "I" (stands for inferior)and the number "1" have the same appearance on the screen when it is in use

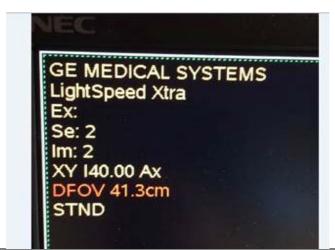
Approximately two weeks ago, the IR Fellow was preparing the patient when he looked at the screen and noted that the "I" said "185". He prepared to mark the patient for biopsy and was off by 10 cms. In this procedure, we aim for millimeters, so this created a huge problem and almost caused an error. This error has been brought to GE's attention for correction, without any action on their part. A patient event was narrowly averted yesterday.

The issue was brought to GE a year ago. They noted the purpose of the "I" in line 6 (XY I40.00 Ax) on the image is to identify if the location on the scan is "inferior" vs "superior." In the example below, I40.00 indicates "inferior" 40.00, not 140. The first character should not be interpreted as a "1" even with its similarity to the "I" because the user needs to know if the location on the patient is inferior or superior.

Manufacturer response for The CT system is system ID CTXTRA, CT system is system ID CTXTRA (per site reporter)

Contact from GE is aware of the issue that we have been having.

Please see picture below:



Catheter, Hemodialysis, Implanted Brand: 12. 5f By 24cm Hemo-cath Lt Model#: MC101243 Lot #: MBHD320 Cat #: MC101243	Medical Components	The screw end of the arterial lumen of the HD catheter has multiple cracks (distal end adjacent to red cap) and it leaks. MD unable to repair it, so patient went to OR to have entire catheter removed and a new one placed. MD states seems to be result of suboptimal material of the screw end (brittle plastic).
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: BD Introsyte –N Lot #: 5027981 Cat #: 384021	BD	When inserting a PICC Catheter to a neonate, and upon removal of introducer, it was noted that the tip of the plastic catheter did not peel away as it was supposed to, and a small piece was still surrounding the catheter. Attempted to remove carefully, but unable to do so without possibly damaging catheter - it is very small, moves freely, and has no sharp edges, so was left in place as high up the catheter as it would go. The catheter and the site were monitored closely, no difficulties were noted. PICC was removed intact with this piece attached. Child was discharged home 2 days later.
Drape, Slush Model#: OEM- ORS-100N Lot #: 1039702	Ecolab Microtek Medical	After finishing the case, we were cleaning the room. As the scrub picked up the drape to throw it away, we noticed it was leaking. There was a hole in the drape.

Slush/warmer Drape Model#: oem- ors-320N Lot #: 1037253 Other #: Sterile Drape Slush 44 x 66	Ecolab Microtek Medical	After the surgery was over and the patient had left the OR, the drapes were being disposed of. When the drape was removed from the slush/warmer machine, there was 20-30 ml of fluid noted in the bottom of the warmer which should not have been there. It is unknown how the fluid got there.
Excavator, Ear Brand: Vantage Metal Ear Syringe Cat #: V919·385	Integra LifeSciences Corporation	An ENT physician was irrigating the patient's ear when the end of the plunger flew off and struck the inner ear. This caused bleeding, but did not damage her ear drum (TM).
Electrosurgical , Cutting, Coagulation Brand: Jarit Model#: 600- 290	Intregra Lifesciences Corporation	During a daVinci robotic case, the laparoscopic cautery cord caught fire. The surgical assistant saw the cautery cord catch fire and the nurse removed the cord from cautery unit. Once the cautery cord plug was removed from the unit, the fire went out. The fire did not spread beyond the cord.

Ethicon	Ethicon	When stapling the appendix, the first load (45 mm standard-blue)
Endopath Ets-	Eulicon	performed without problem. Then the stapler was loaded with a
flex45 Stapler		vascular reload (45mm vascular thin-re). For this instance, the
Duou d.		stapler would not fire and the staples fell out. The stapler hand
Brand: Endopath Ets-		piece appeared intact, so a new reload was placed and this time the stapler half fired and half cut and then became stuck in the closed
flex		position on the patient. After much struggle, the device was able to
		be opened and was removed from the sterile field. The case was
Model#: ATS45		continued, but an additional stapler had to be opened to finish the
A 1 8 4 5 Lot #:		case.
M4J57M		
Needle,	Covidien, Inc.	On several occasions nurses have observed a thin plastic "string"
Hypodermic,	Covidien, me.	alongside the needle which appears to come from the plastic safety
Single		sheath attached to the needle. The string looks to come from a
Brand:		point where plastic was injected into a mold for the safety shield. Nurses in the Intensive Care Unit and Progressive Care Unit have
Magellan		noticed this in at least a half a dozen instances. One device was
111111111111111111111111111111111111111		retained without packaging, a second device was retained with the
Lot #: 526534		packaging. The remainder of the reported devices were discarded at
Cat #: 8881833215		the time of identification. Products are available on site for return and photos of the "string" alongside the needle are available upon
0001033413		request.
l		Please see picture below:

System, Imaging, Pulsed Doppler	GE Healthcare	During a Dobutamine stress test the cardiac ultrasound equipment failed. The screen shut down and would not respond resulting in cancellation of the procedure.
Brand: GE Vivid E9		
Model#: VIVID E9		
VIVID E9		



Links to FDA/CDRH Databases and Other Information Sources



Device Listing: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This database contains a listing of medical devices in commercial distribution by both domestic

and foreign manufacturers.

Establishment Registration: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This is a searchable database of U.S. and foreign establishments engaged in the manufacturer, preparation, propagation, compounding, assembly, or processing of medical devices for U.S. distribution. Note: This database is updated once a month.

Human Factors Website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/HumanFactors/ucm119185.htm. This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Luer Misconnections Website:

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm

This site provides information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other facilitated by the use of Luer connectors.

MAUDE (Manufacturer and User Facility Device Experience):

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Medical Device Safety Website: http://www.fda.gov/cdrh/medicaldevicesafety/
One-stop for safety information with links to published safety tips and articles, archived patient

safety news programs, safety alerts, recalls, and a link to report a device-related problem. **MedSun Website:** http://www.fda.gov/medsun/

This site provides patient safety information via current and past issues of the MedSun newsletter, educational materials, and search capability for MedSun adverse event reports.

Premarket Notifications [510(k)]: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm This database of releasable 510(k) s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information are available via the web interface for more recent records. The database is updated monthly.

Premarket Approvals (PMA): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm This database of premarket approvals of Class III devices may be searched by a variety of fields and is updated on a monthly basis.

Product Classification: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
This database can be used to determine the classification of a device and the regulations it is subject to.

Warning Letters: http://www.accessdata.fda.gov/scripts/wlcfm/recentfiles.cfm This database contains the most recent manufacturer warning letters.

Archived FDA Patient Safety News Stories Available Online

From 2002-2011 "FDA Patient Safety News" (PSN), was a monthly video news show for health professionals. PSN presented information on new product approvals, recalls, and safety alerts, and offered tips on protecting patients. To find out more about the show, read the archived stories, and watch or download the videos please visit: http://www.accessdata.fda.gov/psn/

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